DEC 2 3 2003

K033832

510(k) - Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

1. Device Name and Classification

Product Name:	***syngo Perfusion-CT***
Classification Name:	Accessory to Computed Tomography System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

2. Importer/Distributor Establishment:

Registration Number: 2240869

Siemens Medical Solutions, Inc.
51 Valley Stream Pkwy
Malvern, PA 19355

3. Manufacturing Facility:

Siemens AG
Medical Solutions
Henkestrasse 127

D-91052 Erlangen, Germany

4. Contact Person:

Mr. Rüdiger Körner
Manager Regulatory Submissions
Siemensstr.1; D-91301 Forchheim
Phone: +49 9191 18-9355
Fax: +49 9191 18-9988

5. Date of Preparation of Summary: Oct 15th 2003

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

6. General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

7. Substantial Equivalence:

The **syngo Perfusion-CT** software package that is addressed in this premarket notification, is substantially equivalent to the following commercially available software package

Manufacturer	Product	510(k)	Clearance date
1. Siemens	syngo Perfusion-CT	K982536	Nov. 24, 1998
2. General Electric	CT Perfusion 2	K010042	Jan. 30, 2001

8. Device Description and Intended Use:

Syngo Perfusion-CT is a post-processing software package, which runs on an Intel-based PC platform designed to post-process images acquired with SOMATOM CT scanners, which meet certain minimal requirements (i.e. Siemens Sensation 16, Sensation 10, Sensation Cardiac, Sensation 4, Volume Zoom, Volume Access, Emotion 6, Emotion Duo, Emotion, SOMATOM Plus 4, SOMATOM AR.STAR, SOMATOM Classic). It is a package containing evaluation software that supports the evaluation of Dynamic CT data gathered after the injection of a compact bolus of contrast media, where the contrast media acts as a pure intravascular tracer.

Syngo Perfusion-CT calculates the parameters related to brain perfusion and cerebral blood flow (CBF) using a simple linear relationship between the detected change of signal and the actual concentration of contrast media.

The Siemens syngo Perfusion-CT package has been designed to image cerebral blood flow (CBF), cerebral blood volume (CBV), local bolus timing (i.e. time to start, time to peak) and vascular permeability from sets of images reconstructed from CT data that were continuously acquired after the injection of a bolus of contrast media. It also allows the calculation of mirrored regions of interest and the visual inspection of time density curves.

One potential clinical application is to visualize the apparent brain perfusion in brain tissue affected by acute stroke. Areas of decreased perfusion, as is observed in acute cerebral infarcts, appear as areas of changed image intensity (lower for CBF and CBV, higher for time to peak).

Syngo Perfusion-CT is sensitive in identifying the occurrences of acute stroke during the first 6 hours after onset of symptoms.

A second potential application is the visualization of blood-brain-barrier disturbances in brain tumors. Assessing vascular permeability may improve the differential diagnosis of brain tumors and be helpful in therapy monitoring.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2003

Siemens Medical Solutions, Inc.
% Mr. Stefan Preiss
Responsible Third Party
TÜV America, Inc.
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K033832
Trade/Device Name: syngo Perfusion CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: December 5, 2003
Received: December 10, 2003

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SIEMENS

Attachment 2

Indication for use

510(k) Number (if known): K033832

Device Name: **syngo *Perfusion-CT***

The Siemens syngo Perfusion-CT software package has been designed to evaluate areas of brain perfusion. The software can calculate cerebral blood flow (CBF), cerebral blood volume (CBV), local bolus timing (i.e. time to start, time to peak) and vascular permeability (blood brain barrier disturbances) from sets of images reconstructed from continuously acquired CT data after the injection of contrast media. The package also allows the calculation of mirrored regions of interest and the visual inspection of time density curves.

One potential clinical application is to visualize the apparent blood perfusion in brain tissue affected by acute stroke. Areas of decreased perfusion, as is observed in acute cerebral infarcts, appear as areas of changed signal intensity (lower for CBF and CBV, higher for time to peak).

Syngo Perfusion-CT is sensitive in identifying the areas of decreased perfusion which indicates the occurrence of acute stroke, during the first 6 hours after onset of symptoms.

A second potential application is the visualization of blood-brain-barrier disturbances in brain tumors. A modified Patlak approach is used for the modeling of extra-vascular leakage of blood into the interstitial space. This additional capability may improve the differential diagnosis of brain tumors and be helpful in therapy monitoring.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR §801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033832